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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,564	12/21/2001	Ian A. Wilson	07300-037003	3267
7590 05/10/2004			EXAMINER	
ANITA L. MEIKLEJOHN, PH.D.			ZEMAN, MARY K	
Fish & Richardson P.C.			ART UNIT	
225 Franklin Street			PAPER NUMBER	
Boston, MA 02110-2804			1631	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,564

Applicant(s)

WILSON ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/21/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 7 and 8 are pending in this application. Claims 1-6 have been canceled.

Specification

The amendment filed 4/15/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Tables 3 to be inserted into page 27, setting forth 3D Crystallography coordinates etc. Table 3 does not appear in the parent application and resulting patent, nor is it clear that all of the encompassed information is discussed in the text of the patent such that the entire contents of the table is not new matter. As to tables 1 and 2, while they appear in the parent patent, it is not clear from the record when they were added to that disclosure, nor is it clear that all of the information incorporated therein was described in the specification such that the data is not new matter. Applicant indicates that these tables were a part of the parent application, but a visual inspection of the two (2) Tables in the resulting patent, in comparison with the three (3) Tables in the amendment would indicate that at least one of the tables (Table 3) is completely new, and the information therein is considered new matter. Also the amendment to page 11, line 20 changing "appendix" to "Table 3" is new matter, as no "Table 3" is set forth in the parent specification or the instant specification as filed.

Applicant submits in remarks that an appendix was in the parent application, and therefore this is not new matter. This argument is not persuasive. Applicant has not shown that the ultimate parent possessed this table as now presented, and therefore its addition is new matter. The Examiner is unable to find the term "appendix" in the patented parent application. (US Patent 5,835,382) The only information in table format discussed in the originally filed specification are Tables 1 and 2, also referred to as Tables A and B. There is no discussion apparent in the specification of a table containing all the atomic coordinates for a crystallizes polypeptide. Even if such a reference were found, it is not a discussion of the actual data present in the table. The remarks of Applicant from 4/15/02 indicate that copies of the originally stamped Table were included. Those copies do not appear to be of record, and appear to have been misplaced. It is unclear from the remarks whether a copy of the entire appendix was

submitted, or only a portion. Applicant is requested to resubmit such evidence. The examiner has reviewed the parent file, and has not found this appendix.

Applicant is required to cancel the new matter in the reply to this Office Action.

This application repeats a substantial portion of prior Application No. 08641071, filed 4/26/96, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Information Disclosure Statement

The IDS filed with the application has been entered and reviewed. An initialed copy of the form PTO-1449 is included with this action. It is noted that the following cited patents list the incorrect Inventor: 5,506,107 should be Cunningham et al. (not Mulkerrin et al); 5,436,850 should be Eisenberg et al (not Bowie et al.); and 5,292,654 is Yoshimura et al. (Not Akhiko et al.).

Drawings

The drawings submitted with the application are suitable to the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-6 of U.S. Patent No. 5,835,382. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to EPO mimetics selected by a computer-assisted method.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to unidentified mimetics of erythropoietin which are identified by a computer assisted method. These are product-by-process claims, and the method steps do not appear to materially affect the structure of the product. The claims encompass a genus of compounds defined only by their function, and wherein the function between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using a described assay does not overcome this defect, since one would have no knowledge beforehand as to whether or not any given compound would fall within the scope of what is claimed. No particular mimetics of EPO are disclosed in the specification, nor are any generic classes or

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structures of compounds disclosed as possessing mimetic properties such that one of skill in the art would be able to identify compounds which fall within the scope of the claims. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity. Applicant is further directed to the following trilateral agreement for statements regarding "reach-through" claims: <http://www.uspto.gov/web/tws/sr-3.htm> See Trilateral Project B3b.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is drawn to an EPO mimetic identified by a particular method. However, the steps of the method only identify potential mimetics of EPO (see line 2, and step e). As such, the claim does not actually identify EPO mimetics, and is therefore vague and indefinite as to what is encompasses.

Further in claim 7, the metes and bounds of the limitation "structurally similar" in steps c and d are unclear. How similar must a set of coordinates be to be considered "similar"? The specification is not clear in this regard. How much of a structure is enough to be a "portion" of a structure that is similar? A single atom? An amino acid?

The metes and bounds of claim 8 are unclear, because the ultimate goals are not the same. In line 2, the goal is to identify potential mimetics. Step e has the same result, however, step f2 attempts to actually identify a compound as a mimetic.

Further in Claim 8, there are two steps labeled "f".

Further in claim 8, the metes and bounds of the limitation "structurally similar" in steps c and d are unclear. How similar must a set of coordinates be to be considered "similar"? The specification is not clear in this regard. How much of a structure is enough to be a "portion" of a structure that is similar? A single atom? An amino acid?

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 -8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cunningham et al (USP 5,506,107).

Claims 7 and 8 are drawn to compounds which are identified or selected by a particular computer-assisted process. The compounds are agonists or mimetics of erythropoietin (EPO). Applicant is reminded that in these types of claims, the process of making or selecting the compounds carries little patentable weight.

Cunningham et al. (USP 5,506,107) discloses agonists to EPO, and methods of selecting those agonists using various computer modelling programs. The agonists of Cunningham et al. can be organic, non-proteinaceous compounds as well as amino acid sequence variants” of known agonists of EPO, and other factors. The claims exclude peptides as agonists. The specification appears to define a peptide as a short amino acid sequence of less than about 20 amino acids. Cunningham discloses antibodies which are agonists of various factors, and specifically discusses how to identify such agonists for EPO in columns 12-14. These antibodies do not meet the definition of a peptide, as they are large polypeptide sequences having significant tertiary structure not obtainable with the peptides disclosed in the instant specification. Therefore, Cunningham et al. disclose agonists of EPO, which are not peptides,

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which fall within the scope of the claims, and specifically speak to the identification and testing of small organic molecule agonists for EPO.

The claims are drawn to products identified through a particular process. However, as the process of identification does not appear to materially affect the product, the products of Cunningham et al. are anticipatory.

In a discussion of product-by-process claims, the court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in *In re Best*: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. **Should you have questions on the contents of the electronic file wrapper**, or on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MARY K. ZEMAN
PRIMARY EXAMINER
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5/5/04